

REMARKS

Claims 1-10 are pending. Claims 1 and 2 have been amended. Claims 11 and 12 have been added. No new matter has been added by what of these amendments. Support for the amendments is found in the claims as originally filed. Reconsideration of the pending claims is respectfully requested in view of the amendments above and the remarks below.

Hariwala Does Not Anticipate the Claimed Invention

Claims 1-3, 5-6, and 9-10 stand rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Hariwala, et al. To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Here, the pending claims recite a method of treating impaired filtration or excretion of a solute from a kidney in a patient identified as being in need of the treatment. Hariwala et al. do not teach such an identification step. As such, this reference does not teach each and every limitation of the claimed invention. Accordingly, the cited reference does not anticipate the pending claims. In view of this, Applicants request that the present rejection be withdrawn.

The Claimed invention is Non-Obvious

Claims 1-2 and 9-10 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Guyton in view of Roberts et al.

The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, (Fed. Cir. 1993). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* at 1532. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is

improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Second, there must be a reasonable expectation of success found in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Third, the prior art must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

Here, the Examiner has alleged that Guyton et al. links certain forms of hypertension to certain renal function abnormalities. The Examiner also admits that Guyton does not teach the administration of VEGF to improve filtration or excretion of a solute in the kidney. The Examiner cites to Roberts et al. overcome this deficiency. These references, whether taken alone or in combination fail to teach the claimed invention.

As a preliminary matter, there is no motivation to combine the two references to achieve the claimed invention. The Examiner argued that the impaired secretion of solutes observed in essential hypertension cases would have motivated the combination. This argument omits several other observations made by Roberts et al., such as the inability to determine whether VEGF administration would cause protein efflux as well as small solute efflux. Excretion of protein by the kidney (proteinuria) is an undesirable trait which would dissuade one of ordinary skill in the relevant art from combining these two references. Moreover, the threat of inducing proteinuria using the claimed method would undermine a skilled artisan's belief in a reasonable likelihood of success in practicing the claimed method. Finally, neither reference, whether taken alone nor in combination, teach the identification of a patient suffering from decreased renal solute filtration or excretion. In view of each of these shortcomings, the cited references do not constitute a *prima facie* case of obviousness. Therefore, the present rejection should be withdrawn.

Claims 1-7 and 9-10 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Guyton in view of Roberts et al. and further in view of Zioncheck et al. (U.S. Patent No. 6,485,942). As discussed above, the Guyton and Roberts et al. references do not support a *prima facie* case of obviousness. The Zioncheck et al. reference does not overcome these shortcomings.

Additionally, there is no motivation for one of ordinary to use the heparin-free forms of VEGF, particularly in light of the Roberts et al.'s comments on page 2377, second column, discussing a possible role for the heparin binding character of VEGF in producing fenestrations. In view of this, these cited references fail to support a *prima facie* case of obviousness and thus this rejection should be withdrawn.

Claims 1 and 8 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Guyton in view of Roberts et al. and further in view of Cid et al. (U.S. Patent No. 5,318,957). As discussed above, the Guyton and Roberts et al. references do not support a *prima facie* case of obviousness. The Cid et al. reference was characterized by the Examiner as teaching that angiogenic factors stimulate new blood vessel formation, which can be used to treat various diseases. However, this reference does nothing to cure the deficiencies of the other two references. Additionally, the Cid et al. reference is completely silent as to the use of angiogenic factors for the treatment of renal disorders and hypertension. Thus, the only motivation to combine these references comes from hindsight. In view of this, these cited references fail to support a *prima facie* case of obviousness and thus this rejection should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 219002030902. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By: James J. Mullen
James J. Mullen III, Ph.D.
Registration No.: 44,957
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-7940